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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,149	01/28/2004	Silvio Cavalcanti	07552.0020	2154

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,149	CAVALCANTI ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50 and 95-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *10-16, 18, 21, 25, 28-31, 33, 37-40, 44-46, 97, and 47/10, 18, 21, 25, 28-31, 33, 37-40, 44-46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/20/04, 10/20/04, 11/17/04, 6/3/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-9, 17, 19, 20, 22-27, 32, 34-36, 41-43, 48-50, 95, 96, 98 and 47/1-9, 17, 19, 20, 22-27, 32, 34-36, 41-43 .

DETAILED ACTION

Election/Restrictions

1. Claims 51-94 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 16 February 2006.

Information Disclosure Statement

2. The references cited by applicants in the information disclosure statements filed 20 August 2004, 20 October 2004, 17 November 2004, and 3 June 2005 have been made of record. Examiner has considered the voluminous references to the best of her ability.

3. While the statements filed do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material; rather, they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references. However, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure. *See* Penn Yan Boats, Inc. v. Sea Lark boats Inc., 359 F. Supp. 948, *aff'd* 479 F. 2d. 1338.

4. Applicant is advised that the MPEP states the following with respect to large information disclosure statements:

> *Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability.* MPEP § 609.04(a)(III).

This statement is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888.

The MPEP provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

> *It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See* Penn Yan Boats, Inc. v. Sea Lark Boats, Inc., 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974). *See also* MPEP § 2004.

Therefore, it is recommended that if any information that has been cited by Applicants in the previous disclosure statement is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9, 17, 19, 20, 22-27, 32, 34-36, 41-43, 48-50, 95, 96, 98 and 47/1-9, 17, 19, 20, 22-27, 32, 34-36, 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,866,015 to Kramer et al.

In the specification and the figures, Kramer discloses the apparatus and method as claimed by applicant. In particular, Kramer discloses a method for determining hemodynamic parameters in a system with an arterial branch 20 and venous branch 22 that communicate with fistula or venous access 6, a blood treatment unit or dialyzer 10, and blood pump 26 that moves blood through the fluid transport lines or extracorporeal circuit 9. The device further comprises a memory unit 30, a calculator or processor 35, and a controller 29. The memory, processor, and controller are interconnected and work together to store and process data and control movement of fluid through the circuit. This relationship is regarded as the "control and calculation unit" connected to the "memory" and the first pump claimed by applicant. Furthermore, applicant discloses that the claimed "memory" is not a separate device, but rather incorporated into the control and calculation unit (see paragraph 0081 of specification).

Kramer discloses that processor 35 uses "subfunction 1" and "subfunction 2" to calculate fistula flow (see column 9, lines 1-45). Such a disclosure indicates that the

subfunctions or models are stored in either memory 30 of processor 35. The models comprise a first parameter relating to a characteristic of the vascular access (Q_F), a second parameter relating to at least one characteristic of the blood (T_A), and a third parameter relating to a flow rate of the fluid moved by the pump (Q_B). (See column 7, lines 60-65, column 9, lines 1-43).

The controller, memory unit, and processor disclosed by Kramer cooperate to perform the monitoring procedure claimed by applicant. In particular, the method disclosed by Kramer comprises the steps of varying the delivery rate of blood pump 26 and determining the values of a characteristic of the blood flowing through the circuit (specifically, Kramer discloses measuring the temperature of the blood in the arterial branch) at various times during the pump manipulation, corresponding to applicant's claim drawn to taking a measurement with at least two values of the flow rate. The Kramer method further comprises chronologically storing the values of the blood flow and corresponding temperature in memory unit 30, and processing the stored values via a mathematical subfunction, equation, or model to determine a characteristic of the fistula, namely the flow rate Q_F, through the fistula (see column 8, lines 53-67, column 9, lines 1-45).

With regard to claim 2, the temperature measured by Kramer is a physical property of the blood that correlates with the blood flow rate and is related to the rate in the disclosed equation.

With regard to claim 3, note at least items 24 and 25 of FIG 1 (see at least column 7, lines 27-33) of Kramer, illustrating that temperature measurements may be taken at two points in the extracorporeal circuit 9.

With regard to claim 4, Q_F as disclosed by Kramer is a fluid-dynamic characteristic of the vascular access.

With regard to claims 5-6, Kramer discloses that Q_F may be determined by calculating the solutions of equations 1 and 2. The resulting solution is properly considered the optimal solution claimed by applicant.

With regard to claims 7 and 8, Kramer discloses that the pump 26 is a blood pump and that extracorporeal circuit 9 is connected to a first chamber 12 of a blood treatment device 10 separated by semipermeable membrane (unnumbered dotted line in device 10 in FIG 1). The second chamber 11 of blood treatment device comprises has an outlet connected to drainage line 18 with a discharge pump 19 that removes waste fluid from the blood treatment device.

With regard to claim 9, Kramer discloses that the memory unit stores the constant temperature value of venous temperature measuring device 25 in addition to arterial temperature measuring device 24 (See column 6, lines 55-65). The memory stores values of the temperature and extracorporeal blood flow, and the processor manipulates the stored values to determine a characteristic of the vascular access (see column 8, lines 65-67, column 9, lines 1-43).

With regard to claim 17, Kramer discloses that the mathematical model or equation 1 comprises a parameter related to cardiac output (CO), which is a

characteristic of the systemic circulation of a patient. With regard to applicant's recitation that the control and calculation unit is "predisposed to receive" the parameter, such a limitation does not require that a prior art calculating unit actually receive the desired parameter. All that is required to meet this limitation is a calculating unit that is capable of receiving the claimed data. Kramer's processor is capable of receiving the claimed data, meeting the limitations of the claim.

With regard to claim 19, Kramer's blood circuit 9 is connected to the fistula 6 in a blood withdrawal zone 21 and blood removal zone 23.

With regard to claims 20 and 22, the arterial temperature sensor 24 is located between blood withdrawal zone 21 and pump 26, making it upstream of pump 26(see FIG 1). The measured values are stored in memory 30, indicating that the combined memory and control unit of Kramer emits a signal corresponding to the detected value so that the value may be stored in the memory.

With regard to claims 23 and 27, applicant's recitation that the sensor is "predisposed" to operate in the blood withdrawal or return zone does not require the placement of the sensor in the blood withdrawal or return zone. It only requires that the sensors of the prior art are capable of operating within the blood withdrawal or return zone. Kramer's sensors are capable of operating in the location claimed by applicant, meeting the limitations of the claims.

With regard to claims 24 and 26, the venous temperature sensor (T_V) is located between pump 26 and blood return zone 23, downstream of blood treatment device 10. The measured values are stored in memory 30, indicating that the combined memory

and control unit of Kramer emits a signal corresponding to the detected value so that the value may be stored in the memory.

With regard to claim 32, Kramer discloses that the "first parameter" may comprise Q_F, flow into and out of the fistula, which corresponds to applicant's q_f.

With regard to claim 34, applicant's recitation that the calculation unit is "predisposed to receive" signals does not require that prior art calculation units actually receive the signals as claimed. It only requires that the calculating units of the prior art are capable of receiving signals from the extracorporeal circuit. Kramer's calculating unit is capable of receiving the signals claimed by applicant, meeting the limitations of the claim.

With regard to claims 35-36, note that Kramer discloses a second mathematical model (see equation 2 and note description of its function, at least column 8) that may be used to calculate a characteristic of the blood in the extracorporeal circuit, which includes the withdrawal zone.

With regard to claim 41, applicant's recitation that a device is "predisposed to" emit a particular signal does not require that prior art devices actually emit the signals as claimed. It only requires that devices of the prior art are capable of emitting signals from the extracorporeal circuit. Kramer discloses a display 37 that is capable of emitting signals related to extracorporeal blood flow, thereby meeting the limitations of the claim.

With regard to claim 42, Kramer discloses measuring the temperature of the blood in the arterial branch) at various times during the pump manipulation. The Kramer method further comprises chronologically receiving and storing the values of the blood

flow and corresponding temperature in memory unit 30, and evaluating and processing the stored values via a mathematical subfunction, equation, or model to determine a characteristic of the fistula, namely the flow rate Q_F, through the fistula (see column 8, lines 53-67, column 9, lines 1-45).

With regard to claim 43, Kramer discloses that the memory unit stores the constant temperature value of venous temperature measuring device 25 in addition to arterial temperature measuring device 24 (See column 6, lines 55-65). The memory stores values of the temperature and extracorporeal blood flow, and the processor manipulates the stored values to determine a characteristic of the vascular access (see column 8, lines 65-67, column 9, lines 1-43).

With regard to claim 47/1-9, 17, 19, 20, 22-27, 32, 34-36, 41-43, Kramer discloses a display 37 that examiner regards as the claimed monitoring apparatus.

With regard to claim 48, Kramer discloses that the device may perform hemodialysis or other hemotherapy (see column 1, lines 15-30).

With regard to claim 49, Kramer discloses that the temperature and flow rate measurements are stored "chronologically" in memory unit 30 (see column 8, lines 65-67) and that the monitoring procedure operates at least once during the extracorporeal treatment time (see column 9, lines 53-63). Therefore, the Kramer device necessarily includes a timing device as recited.

With regard to claim 50, applicant's recitation that the calculation unit is "predisposed to" operate in a manual or automatic mode does not require that prior art calculation units actually operate as claimed. It only requires that the calculating units of

the prior art are capable of operating in a manual or automatic mode. Kramer's calculating unit is capable of operating either manually or automatically, meeting the limitations of the claim.

With regard to claim 95, the method disclosed by Kramer comprises the steps of varying the delivery rate of blood pump 26 and determining the values of a characteristic of the blood flowing through the circuit (specifically, Kramer discloses measuring the temperature of the blood in the arterial branch) at various times during the pump manipulation, corresponding to applicant's claim drawn to taking a measurement with at least two values of the flow rate. The Kramer method further comprises chronologically storing the values of the blood flow and corresponding temperature in memory unit 30, and processing the stored values via a mathematical subfunction, equation, or model to determine a characteristic of the fistula, namely the flow rate Q_F, through the fistula (see column 8, lines 53-67, column 9, lines 1-45).

With regard to claim 96, the models comprise a first parameter relating to a characteristic of the vascular access (Q_F), a second parameter relating to at least one characteristic of the blood (T_A), and a third parameter relating to a flow rate of the fluid moved by the pump (Q_B). (See column 7, lines 60-65, column 9, lines 1-43).

With regard to claim 98, the method comprises receiving the temperature values and blood flow rate values at discrete periods in time, meaning that the Kramer device receives at least 4 processed values in performance of the monitoring method.

Allowable Subject Matter

7. Claims 10-16, 18, 21, 25, 28-31, 33, 37-40, 44-46, 97, and 47/10, 18, 21, 25, 28-31, 33, 37-40, 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the limitations of the base claim in combination with the elements set forth below.

With regard to claims 10-16 and 47/10-16, Kramer discloses a second pump 19 in communication with the dialysis fluid, but does not disclose that the mathematical model of the vascular access comprises a parameter relating to the flow of fluid through the second pump.

With regard to claims 18 and 47/18, Kramer does not disclose the use of arterial pressure to calculate fistula flow.

With regard to claims 21, 25, 28-31, and 47/21, 25, 28-31, Kramer does not disclose the use of a pressure sensor anywhere in the apparatus or mathematical model to measure a parameter of the fluid flowing through the circuit. Kramer also does not disclose the measurement or manipulation of a parameter relating to blood pressure.

With regard to claims 33, 44, 97, and 47/33, 44 Kramer does not disclose the claimed equation nor any measurement or manipulation of pressure in the patient or the extracorporeal circuit.

With regard to claims 37-40 and 47/37-40, Kramer fails to disclose a 3rd mathematical model or equation as recited by applicant.

With regard to claims 45, 46, and 47/45, 46, Kramer fails to disclose that the controller maintains the pumping rate at a steady state or changes the flow rate of second pump 19.

Conclusion

9. No additional art beyond what is cited in the IDS and referenced in the Office Action is considered pertinent to the disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie R. Deak
Patent Examiner
Art Unit 3761
12 April 2006

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